



DEPARTMENT OF HEALTH AND HUMAN SERVICES

54177d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 25, 2003

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-23

James M. Henry, Owner
Aloha Juice Company
935 SE Belmont
Portland, Oregon 97214

WARNING LETTER

Dear Mr. Henry:

On April 3, 2003, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 935 SE Belmont, Portland, Oregon. During the inspection, our investigator collected labels for three of your juice products and found them to be in violation of Section 403 (a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21 of the Code of Federal Regulations 21 CFR Part 101- Food Labeling. You can find this Act and the Food Labeling regulations through links in FDA's homepage at www.fda.gov.

The deviation found is as follows:

The products are misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) in that the term "Fresh," which appears on the labels of "100% Natural Lemonade," "100% Natural Orange Juice," and "100% Natural Grapefruit Juice" is false because the products have been pasteurized by Sun Orchard. Furthermore, title 21, Code of Federal Regulations (21 CFR), section 101.95 does not permit the term "Fresh" to be used on juice products that have been pasteurized.

The above violation concerns labeling requirements but is not meant to be an all-inclusive list of deficiencies on your label or in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

James M. Henry, Owner
Aloha Juice Company, Portland, Oregon
Re: Warning Letter SEA 03-23
Page 2

Please respond in writing within three (3) weeks from your receipt of this letter.

Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Additional Comments:

We also note the following regarding your labeling:

- The term "pasteurized" must be included on the principal display panel as part of the name of orange juice products that have been pasteurized, as required by 21 CFR §§ 101.3(a), (d) and 146.140(d)(1).
- Your product labeled as "100% Natural Lemonade" includes the ingredients "natural cane or fruit sugars" on its ingredient statement. All ingredients must be listed in the ingredient statement by their common or usual name, as required by 21 CFR §101.4. The regulations do not provide for the use of "and/or" labeling for sugars in juice products.
- The label of a beverage (e.g., Lemonade) which is required to bear a percent juice declaration and is less than 100% juice may not contain any other percentage declaration that describes the juice content of the beverage, such as "100% natural," as provided in 21 CFR 101.30(l).

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any question regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4813.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:

Section 403 of the FD&CA Act
21 CFR Part 101, Section 101.4 and 101.5

cc: WSDA with disclosure statement